K02 2239

AUG 2 3 2002

510(k) Summary
for
Surgetics ENTact Endonasal Navigation System

1. Submitter Name and Address

Praxim
"Le Grand Sablon"
4, Avenue de l'Obiou
38 700 La Tronche
France

Contact Name: Stéphane Lavallée
Telephone: 33-4 76 54 95 03

Date Prepared: July 10, 2002

2. Device Name

Proprietary Name: Surgetics ENTact Endonasal Navigation System
Common/Usual Name: Image guided surgical navigation system
Classification Name: Computed tomography x-ray system (accessory)

3. Predicate Device

Marconi Medical Systems Voyager (K000310)

4. Intended Use

The Surgetics ENTact Endonasal Navigation System is intended for use as an aid to the surgeon for precisely locating anatomical structures either during open or percutaneous ENT/endonasal or sinus procedures.

5. Device Description

The Surgetics ENTact Endonasal Navigation System is specifically designed for use in ENT/endonasal and sinus procedures. It allows the surgeon to locate surgical instruments (e.g., aspirator) on three planes (axial, sagittal, frontal) on a pre-operative CT scan in real-time. The system uses an infrared camera for localization and guidance of the surgical instrument. Additionally, a surgical planning capability

using the Consultics Station is provided which allows the surgeon to pre-operatively plan the surgery.

6. Technological Characteristics and Substantial Equivalence

The Surgetics ENTact Endonasal Navigation System is substantially equivalent to other predicate image-guided systems (e.g., Marconi Voyager, K000310) that are currently marketed. It is similar to the other image-guided systems in its technological characteristics. It uses the same type of optical infrared system for instrument tracking and localization as other previously cleared image-guided systems. Like the predicate products, it includes tools and accessories that are used during the procedure and require sterilization prior to use. The various predicate image-guidance systems use a variety of methods for registration of the alignment of the patient with an image. The Surgetics uses a frameless system that doesn't require pre-operative scanning of fiducial markers. Registration is achieved prior to surgery by simply mapping multiple points or areas on the patient's face using a special ball pointer mapping probe. The mapped points are then registered with the corresponding points on a 3-D CT image of the patient's face.

7. Performance Testing

The Surgetics ENTact Endonasal Navigation System was tested for compliance with electrical safety and electromagnetic compatibility standards. In addition, summaries of accuracy testing using phantoms and clinical experience with the system were provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2002

Praxim, "Le Grand Sablon"
c/o Sheila Hemeon-Heyer, J.D., RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K022239
Trade/Device Name: Surgetics ENTact Endonasal Navigation System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: July 10, 2002
Received: July 11, 2002

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K022239

510(k) Number (if known):

Device Name: Surgetics ENTact Endonasal Navigation System

Indications for Use:

The Surgetics ENTact Endonasal Navigation System is intended for use as an aid to the surgeon for precisely locating anatomical structures either during open or percutaneous ENT/endonasal or sinus procedures.

(Please do not write below this line –Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022239

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)